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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,178	01/13/2004	Fred H. Burbank	R0367-00702	2089

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/756,178

Applicant(s)

BURBANK ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 20, 22-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 22 and 23 is/are allowed.
- 6) ☒ Claim(s) 19, 20, 25-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2007 and 05 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received July 21, 2006, have been fully considered by the examiner. In particular, it is noted that applicant has removed the priority claim to several of the previously filed applications/patents. The following is a complete response to the July 21, 2006 communication.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device having a tissue separator/isolator, an encapsulation means and a damaging means must be shown or the feature(s) canceled from the claim(s). Also, there is no discussion of reference number "428" in the specification. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Also, the drawing amendment filed January 29, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: there has been no disclosure of a device as shown in newly added Figure 12 that includes the radio frequency wires (labeled 428, but not described in the specification).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20 and 25-34 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application, as originally filed, failed to disclose the specific combination of steps including separating a tissue specimen, encapsulating the separated tissue and damaging the separated tissue specimen as now set forth in independent claim 19. Also, the specification does

not disclose a device including separate tissue cutting, tissue encapsulating and tissue damaging devices as now set forth in independent claim 30.

While the instant specification has been amended to include subject matter from related US Patent No. 6,344,026 directed towards a tissue encapsulation device, there is nothing in the instant disclosure or any of the other related documents to support the cutting/separation, encapsulation and damaging of tissue. The instant specification as originally filed (i.e. without the subject matter of the '026 patent incorporate therein) discloses only the cutting/separation of tissue with the subsequent damaging of the tissue. Page 10 of the specification indicates that Figure 6 shows a "tissue specimen isolating and damaging device" that has a morcellator to morcellate tissue. The specification then states "The tissue specimen may be morcellated after encapsulation of the tissue specimen." This is the only support found that suggests that all three modalities (i.e. separation, encapsulation and damaging) may be performed in the same procedure. However, there is no specific description of how the encapsulation is performed using the tissue isolating and damaging device as shown in Figure 6. The tissue encapsulation device of Figures 9 and 10 fails to disclose a tissue separating and/or tissue damaging means. It seems the only logical way to provide the three separate treatment modalities based on applicant's disclosure would be to insert the device of Figure 6 to isolate/cut tissue, remove that device, insert the device of Figure 9 to encapsulate the tissue, remove that device, then re-insert the Figure 6 device to morcellate/damage the tissue. However, there is no disclosure of such a series of steps,

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and it seems counterintuitive to the process that allows for the treatment and removal of biopsy tissue with a single device.

It is noted that other related US Patents, such as US Patent No. 6,331,166, indicates that encapsulation of tissue is an alternative treatment to the isolation and damaging of tissue (see Abstract). Also, US Patent No. 6,344,026, which is the subject matter incorporated into the instant specification to provide support for the encapsulation embodiments of Figures 9 and 10, does not disclose the isolation and/or damaging of tissue as now recited in the instant application claims. There is no suggestion in the instant application description or in any of the related applications and patents that all three modalities (isolation, encapsulation and damaging) are performed in the same procedure with the same device.

It is further noted that US Patent Numbers 6,659,105 and 6,676,658 (from which the instant application is a direct continuation) suggest alternative embodiments where "the tissue specimen is damaged by encapsulation" or "the tissue may be physically isolated by encapsulation". This recitation merely implies that two modalities are one and the same, and does not provide explicit support for performing three separate steps with three separate means as is now recited in claims 19-21 and 25-39.

Response to Arguments

Applicant's arguments with respect to the 35 USC 112, first paragraph issues have been fully considered but they are not persuasive. It is noted that the prior art rejections have been withdrawn in view of applicant's amendments to the claims.

With regard to newly added Figure 12 and the associated amendment to the specification, the examiner maintains that this figure does not show the three distinct elements set forth in the claims, namely the separating means, the encapsulating means and the damaging means. There is no mention whatsoever of an encapsulation means in the newly added subject matter describing newly added Figure 12. There is also no discussion of a damaging means, and it appears as though the cutting member is used to separate (i.e. isolate tissue). The addition of elements 428 is deemed to present new matter since the original Figure 4 in the '026 patent did not have any "damaging" elements. Applicant has also pointed out this issue on page 10 of the January 29, 2007 response.

The examiner maintains that applicant has not sufficiently shown support for all three of the aforementioned elements in a single embodiment. That the instant disclosure, as well as the disclosures of the related applications/patents, makes mention of the three elements is not disputed. However, as addressed in the rejection, it is not clear what is the distinction of a separating means, or an isolation means, or an encapsulating means. The specification and the related application/patent specifications seem to use these terms interchangeably and there is no clear distinction as to what elements are used to perform these different functions. It is the examiner's position that applicant is piecing together portions of the specification that make mention of these different elements, but that the specification as a whole fails to clearly and expressly disclose a single embodiment which includes a tissue separator (or isolator), an encapsulating device and a damaging device. Again, the inclusion of elements (428)

in the newly added Figure 12 is deemed to present new matter, particularly since the incorporated subject matter from the ('026) patent clearly did not teach such elements and further since applicant's disclosure did not specifically support the use of such elements in the device of the ('026) patent.

Conclusion

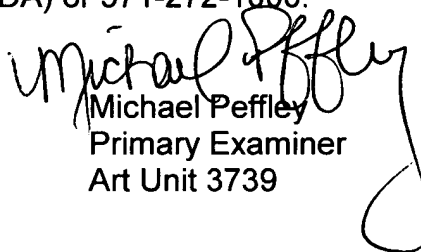
Claims 1, 22 and 23 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 26, 2007